CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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QMS15-A

Assessments: Laboratory Internal Audit Program; Approved Guideline

This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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Assessments: Laboratory Internal Audit Program; Approved Guideline

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Abstract

Clinical and Laboratory Standards Institute document QMS15-A—*Assessments: Laboratory Internal Audit Program; Approved Guideline* provides recommendations for establishing an internal audit program and related processes for enhanced quality and continual improvement in the laboratory. The audit program defines the "who," "what," "when," "where," and "how" of the laboratory's intent to audit its work, whereas the audit process describes how the act of tracing samples and records through laboratory workflow processes can identify areas of noncompliance and opportunities for improvement. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.

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Foreword

NOTE:

The word **"audit"** should not be used interchangeably with the terms assessment, inspection, or survey, as they are **not the same thing!**

In the QMS, Assessments is one of the 12 quality system essentials (QSEs) described in CLSI document QMS01,[1] which defines a structured approach to organizing, creating, and maintaining the necessary information for the QSEs. The QMS model depicted in Figure 1 demonstrates how each QSE, including Assessments, is a building block to quality and necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

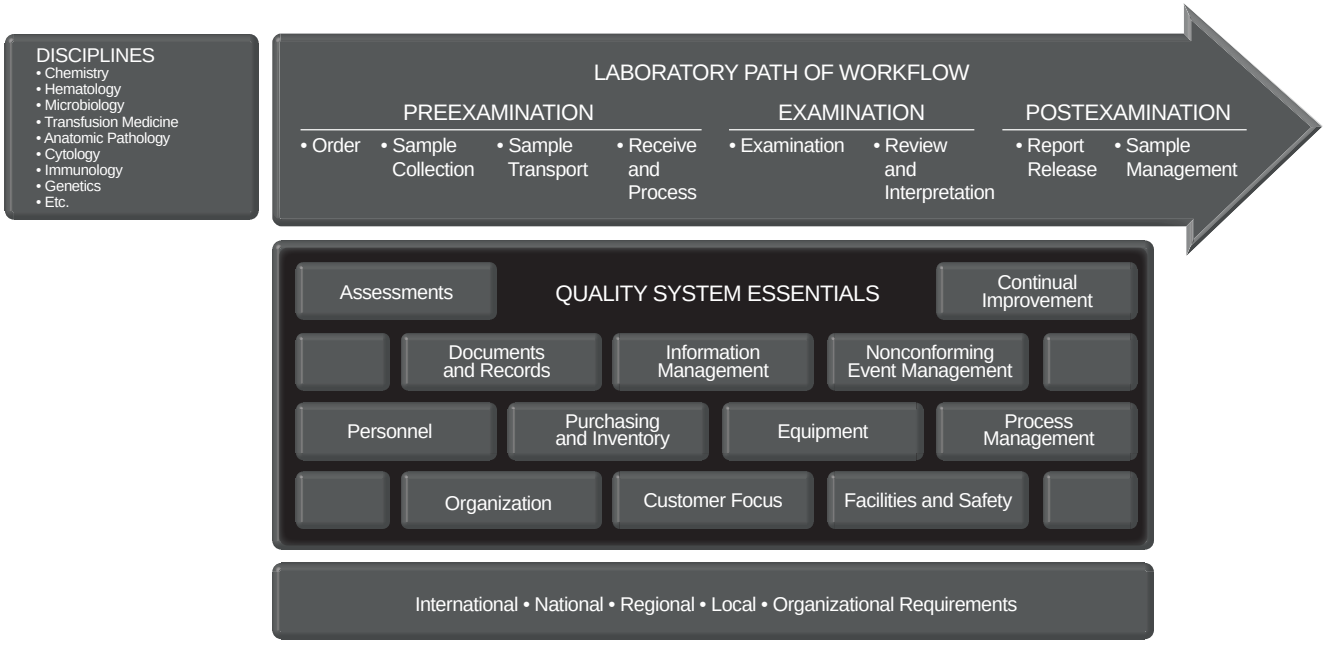

Figure 1. The Quality Management System Model (see CLSI document QMS01)[1]

A laboratory audit program is critical to ensuring the laboratory meets applicable requirements. QSE Assessments encompasses both internal and external assessments, with separate elements for each (see Figure 2). This document provides guidance for implementing an internal audit program.

KEY WORDS

Assessment

Audit

Audit program

Inspection

Internal audit

Quality management system

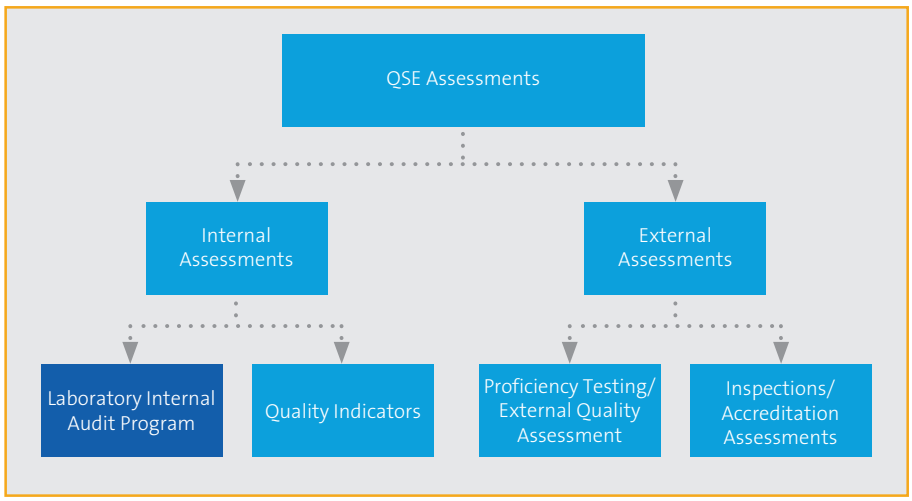

Figure 2. Components of QSE Assessments

Chapter 1

Introduction

This chapter includes:

- Document scope and applicable exclusions
- Background information pertinent to the document content
- Standard Precautions information, as applicable
- Terms and definitions used in the document
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions, where applicable
- Abbreviations and acronyms used in the document

Assessments: Laboratory Internal Audit Program; Approved Guideline

1 Introduction

NOTE:

Internal audits of laboratory processes **provide objective evidence of nonconformances and risks** that can affect the quality of laboratory services and patient safety.

1.1 Scope

This guideline is intended for use by laboratory leaders such as directors, managers, and supervisors, and other individuals associated with laboratories that perform medical testing. This document focuses on using a laboratory internal audit program to actualize the laboratory's commitment to quality, good professional practice, and continual improvement, by identifying problematic processes.

The examples provided are applicable to laboratories of any size and functional complexity. Some examples provided in both the text and the appendixes are not intended to be complete, but rather are abbreviated to clarify the material being presented.

IMPORTANT NOTE:

The laboratory internal audit **program** described in this guideline is **scalable to any size laboratory.**

1.2 Background

Internal auditing of work practices is an important QMS tool that helps a laboratory meet regulatory, accreditation, and customer requirements. Internal audits of laboratory samples, documents, and records provide objective evidence of nonconformances and risks that can affect the quality of laboratory services and patient safety. The identified nonconformances improve laboratory services through corrective actions while the identified risks provide opportunities for improvement. Internal audit programs can also identify positive practices that can be replicated within the laboratory environment and affirm compliance with requirements.

This guideline has adapted successful models used in business and industry and made them applicable to medical laboratories. It describes the use of an internal audit program and related processes for achieving enhanced quality and continual improvement in the clinical laboratory. An internal audit program and related processes are scalable to any size laboratory and require only the laboratory leadership's and staff's willingness to compare current practice to expectations.

The audit **program** defines the "who," "what," "when," "where," and "how" of meeting requirements for internal auditing, and the audit **process** describes the details of how to conduct individual laboratory internal audits. Committed laboratory leadership and individuals willing to share their expertise and experience will enable a successful internal audit program.